

ABSTRACT

A method by which a freeze-drying process may be developed from a single freeze-drying experiment. The method uses in-process manometric temperature measurement (MTM) data to optimize the primary drying conditions. Manometric temperature measurement is a procedure by which the product temperature at the sublimation interface and the resistance of the previously dried product to vapor flow may be determined. The inventive method can be used in an inventive freeze-drying system. The system comprises a freeze-dryer, a measurement system including hardware and software necessary for generation of MTM data and a control system including hardware and software for interpretation of the generated MTM data and control of the freeze-dryer. The measurement system and control system may be combined into a single device. The inventive freeze-drying system utilizes a microprocessor and software to define conditions for the freezing and secondary drying stages and to define chamber pressure and "target product temperature" for the primary drying stage based on MTM data and operator input data, thereby providing a near optimized freeze-drying process.